

Application No. 09/553,573
Amendment April 24, 2007
Reply to Office Action of March 27, 2007

REMARKS

Applicant amended independent claims 1, 102, and 147 to further define Applicant's claimed invention. Support for the amendments to claims 1, 102 and 147 can be found at least in FIGS. 4 and 5 of the application.

In the Office Action, the Examiner rejected all of the claims on the ground of nonstatutory obviousness-type double patenting as being unpatentable over all of the claims of U.S. Patent No. 6,666,890 and all of the claims of U.S. Patent No. 7,022,137. Applicant is submitting concurrently with this Amendment a Terminal Disclaimer of the terminal part of any patent granted in the present application which would extend beyond the expiration of U.S. Patent Nos. 6,666,890 and 7,022,137. Applicant submits that the obviousness-type double patenting rejection has been overcome.

The Examiner rejected claims 1, 2, 4-8, 11-34, 36-38, 40-42, 101-130, 132-135, and 137-174 under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,113,638 to Williams et al. ("Williams"). Independent claims 102 and 147 recite that the exterior facing side wall includes "a straight portion along the length of said implant." Applicant amended independent claim 1 to recite an exterior facing side wall "including a straight portion along the length of said implant." Independent claim 1 recites "an interior facing side wall, an exterior facing side wall opposite said interior facing side wall . . . said interior and exterior facing side walls extending between said opposed portions." Applicant amended independent claims 102 and 147 to recite "said interior and exterior facing side walls extending between said opposed portions." In addition, independent claims 1, 102, and 147 each recite that the leading end of the implant includes "a curved portion extending from the junction of said leading end and said exterior side wall to at least the intersection of said leading end and the mid-longitudinal axis of said implant." Williams does not disclose or suggest such recitations.

In the only embodiment including a pair of implants installed in a side-by-side relationship described in Williams (illustrated in FIG. 2), the exterior facing sidewall of each implant 30 and 32 is either circular or oval. (See col. 5, lines 51-54). Williams does

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not teach an exterior facing sidewall of each of the implants that includes a straight portion along the length of the implants as recited in independent claims 1, 102, and 147.

Applicant respectfully maintains the position traversing the Examiner's statement that "it is within the teaching of Williams et al. that making a hemi-device applies to all taught embodiments" (Office Action, page 7) for reasons set forth on page 21 of the Amendment dated January 19, 2007, incorporated by reference herein. Applicant submits that even if the single implant embodiments of FIGS. 5A and 7A were each improperly deconstructed into two side-by-side implants, Williams still would not disclose or suggest all of the recitations of independent claims 1, 102, and 147 for reasons discussed below.

As shown in FIGS. 5A and 7A, the interior of the implants is hollow. If the embodiments of FIGS. 5A and 7A were to be divided into two implants, the interior sides would be open such that neither one of the resulting implants would have an interior side wall extending between the upper and lower portions of the implants as recited in independent claims 1, 102, and 147.

FIGS. 5A and 7A of Williams show an implant with a trailing end having channels 107, 109 and 145, 147, respectively, and an opposing leading end having a partly linear portion extending from the junction of the leading end and the exterior sidewall to the intersection of the leading end and the mid-longitudinal axis of each implant. If any one of the implants of FIGS. 5A and 7A of Williams were deconstructed into two implants, neither one of the resulting implants would have a leading end with a curved portion extending from the junction of said leading end and said exterior side wall to at least the intersection of said leading end and the mid-longitudinal axis of said implant as recited in independent claims 1, 102, and 147.

Applicant respectfully disagrees with the Examiner's statement that "the leading end can be interpreted as either the end containing opening 107 or the opposite end." (Office Action, page 6). Applicant submits that the leading and trailing ends in the implants taught by Williams are different and not interchangeable, and that the implants are inserted intradiscally with the leading end always being inserted first. The trailing end

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of the implant shown in FIG. 5A of Williams has a channel 109 "configured to receive a screw therethrough for causing the anchoring elements 108 to be pushed into the end plates of adjacent vertebrae." (col. 7, lines 43-46). The trailing end of the implant shown in FIG. 7A of Williams has a "channel formed by holes 145 and 147," through which "a fixation screw 146 can be used to drive the wedge 144 which pushes the anchor plates 132 and 134 toward end plates of adjacent vertebrae... and securing the device 130 intradiscally." (col. 8, lines 32-37). The leading ends of the implants of FIGS. 5A and 7A do not have such channels for receiving fixation screws.

If the implants of FIGS. 5A and 7A were to be improperly inserted with the trailing ends first, the channels would not be accessible to the surgeon to permit insertion of fixation screws therethrough. Moreover, the reversed orientation of the implants relative to the vertebral bodies would no longer conform the implants to the natural shape of the vertebral bodies, thus becoming less desirable for their intended purpose.

Regarding the 35 U.S.C. § 103(a) rejection over Williams, Applicant submits that the Examiner has not provided any teaching or suggestion in Williams indicating that it would have been an obvious matter of design choice to employ a spinal implant with an exterior facing sidewall being at least in part linear along the length and a leading end including a curved portion extending from the junction of the leading end and the exterior side wall to at least the intersection of the leading end and a mid-longitudinal axis of the implant as claimed by Applicant. Williams teaches two distinct embodiments of the implant – a hemi-implant embodiment (FIG. 2), and full-size embodiments (FIGS. 1 and 3A-8B). Williams does not teach that full-size embodiments can be deconstructed to form the hemi-implant embodiment or *vice versa*. Also, the Examiner has failed to show any teaching or suggestion in Williams to deconstruct the single implant embodiments shown in FIGS. 5A and 7A into the side-by-side implants embodiment shown in FIG. 2.

According to MPEP § 2142, "impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art." A *prima facie* case of obviousness cannot be based on hindsight applied after a contemplation of Applicant's disclosure. Applicant submits that one skilled in the art

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would not be motivated to split the single implant of Williams into two side-by-side implants when a side-by-side implant embodiment is already disclosed in Williams. Applicant also submits that splitting the implants of FIGS. 5A and 7A into hemi-implants would interfere with the internal mechanisms (e.g., 144 in FIG. 7A) for each embodiment and would render the implants inoperable for their intended purpose. As such, Applicant respectfully submits that the Examiner applied impermissible hindsight in the combination forming the basis of the rejection under 35 U.S.C. § 103(a). Accordingly, it is submitted that the Examiner has not made a showing of a *prima facie* case of obviousness.

Applicant submits that the rejections under 35 U.S.C. § 102 and § 103(a) over Williams are deemed to be overcome. Applicant submits that independent claims 1, 102, and 147 are patentable and that dependent claims 2, 4-8, 11-34, 36-38, 40-42, 101, 103-130, 132-135, 137-146, and 148-174, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

The Examiner rejected claims 1, 2, 4-8, 11-34, 36-38, 40-42, 101-130, 132-135, and 137-174 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,609,635 to Michelson ("Michelson '635") in view of U.S. Patent No. 5,192,327 to Brantigan ("Brantigan"). Applicant amended independent claim 1 to recite an artificial interbody spinal implant having an exterior facing sidewall "including a straight portion along the length of said implant." Independent claims 102 and 147 recite that "said exterior facing side wall" includes "a straight portion along the length of said implant." In addition, independent claims 1, 102, and 147 each recite that the leading end of the implant is "asymmetrical."

FIG. 2 of Michelson '635 illustrates the leading end 120 of the implant as a substantially straight line that is symmetrical from side to side. FIG. 2 of Brantigan shows the leading end 21 of the implant as a straight line that connects to a circular sidewall. The straight leading end is symmetrical from side to side. Neither Michelson '635 nor Brantigan, alone or when properly combined, teach or suggest an implant having a leading end that is asymmetrical as recited in independent claims 1, 102, and 147.

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Further, the spinal implant in FIGS. 1-17 of Michelson '635 is a full-size embodiment which the Examiner admits "does not teach the implant being less than approximately one-half the maximum width of the adjacent vertebrae." (Office Action, page 8). Brantigan expressly teaches that the hemi-implant embodiment of FIG. 2 includes a "round oval end wall 21b." (col. 4, lines 62-63). Brantigan does not teach that the exterior facing sidewall of either the full-size or the hemi-implant embodiment is at least in part linear along the length of the implant. Thus, Michelson '635 and Brantigan, either alone or when properly combined, do not disclose or suggest an interbody spinal implant having an exterior facing sidewall that is at least in part linear along the length as recited in independent claims 1, 102, and 147.

Applicant respectfully maintains the position with respect to the Examiner's asserted motivation to combine Michelson '635 with Brantigan for reasons set forth on page 22 of Applicant's Amendment dated January 19, 2007, incorporated by reference herein. Nonetheless, Applicant amended independent claim 1 in order to expedite the prosecution of this application. Applicant submits that the rejection of claims 1, 102, and 147 under 35 U.S.C. § 103(a) as being unpatentable over Michelson '635 in view of Brantigan has been overcome.

Applicant submits that independent claims 1, 102, and 147 are patentable and that dependent claims 2-34, 36-42, 101, and 103-174, dependent from one of independent claims 1, 102, and 147, respectively, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, it is respectfully submitted that the claims, as amended, are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees

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required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,

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